

12-16-99

A/Reissue

Practitioner's Docket No. 498-53 CON/RES**PATENT****IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**Date: December 15, 1999Assistant Commissioner for Patents
Washington, D.C. 20231

jc542 U.S. PTO

09/464610

12/15/99

REISSUE APPLICATION TRANSMITTAL

Transmitted herewith is the application for reissue of U.S.

☒ Utility Patent ☐ Plant Patent ☐ Design Patent
 No. 5,697,970 issued on December 16, 1997

Inventor(s): Schmitt, et al.Title: THINLY WOVEN FLEXIBLE GRAFT

Enclosed are the following:

1. Specification, claim(s) and drawing(s) (37 C.F.R. § 1.173)

- (a) ☒ 5 page(s) of specification
☒ 5 page(s) of claims
☒ 1 page(s) of abstract

NOTE: This must include the entire specification and claims of the patent, with the matter to be omitted by reissue enclosed in square brackets. Any additions made by the reissue must be underlined, so that the old and new specifications and claims may be readily compared. Claims should not be renumbered. The numbering of claims added by reissue should follow the number of the highest numbered patent claim. No new matter shall be introduced into the specification. (37 C.F.R. § 1.173).

CERTIFICATION UNDER 37 C.F.R. § 1.10*

(Express Mail label number is mandatory.)

(Express Mail certification is optional.)

I hereby certify that this Reissue Application Transmittal and the documents referred to as enclosed therein are being deposited with the United States Postal Service on this date December 15, 1999, in an envelope as "Express Mail Post Office to Addressee," mailing Label Number EJ279940144US addressed to the: Assistant Commissioner for Patents, Washington, D.C. 20231.

M J Mullin
 (type or print name of person mailing paper)

M J Mullin
 Signature of person mailing paper

WARNING: Certificate of mailing (first class) or facsimile transmission procedures of 37 C.F.R. § 1.8 cannot be used to obtain a date of mailing or transmission for this correspondence.

***WARNING:** Each paper or fee filed by "Express Mail" **must** have the number of the "Express Mail" mailing label placed thereon prior to mailing. 37 C.F.R. § 1.10(b).

"Since the filing of correspondence under § 1.10 without the Express Mail mailing label thereon is an oversight that can be avoided by the exercise of reasonable care, requests for waiver of this requirement will **not** be granted on petition." Notice of Oct. 24, 1996, 60 Fed. Reg. 56,439, at 56,442.

(Reissue Application Transmittal [17-1]—page 1 of 6)

jc525 U.S. PTO
12/15/99

09464610-121599

(b) ☐ _____ sheet(s) of drawing (drawings amended)

☐ Formal

☐ Informal

NOTE: "Amendments which can be made in a reissue drawing, that is, changes from the drawing of the patent, are restricted." 37 C.F.R. § 1.174(b).

☒ No changes in the drawings, upon which the original patent was issued, are to be made. Therefore, in accordance with 37 C.F.R. § 1.174(a), please find attached, in the size required for original drawings:

☒ a copy of the printed drawings of the patent.

☐ a photoprint of the original drawings.

☒ A letter requesting transfer of the drawings from the original patent file to this reissue application is attached.

2. Declaration and power of attorney

☒ 6 pages of declaration and power of attorney

3. Preliminary amendment

(check, if applicable)

☐ Attached

4. Offer to surrender the original letters patent in accordance with 37 C.F.R. § 1.178 is attached.

☒ Offer to surrender is by the inventor

☒ along with assent of assignee.

☐ Offer to surrender is by the assignee of the entire interest (and the reissue application does not seek to enlarge the claims of the original patent).

5. Letters patent

☐ Original letters patent are attached.

☐ Declaration that original letters patent lost or inaccessible is attached.

☒ A copy of the original printed patent is attached.

NOTE: "The application may be accepted for examination in the absence of the original patent or the declaration but one or the other must be supplied before the case is allowed." 37 C.F.R. § 1.178.

NOTE: "Where the original patent grant is not submitted with the reissue application as filed, patentee should include a copy of the printed original patent. Presence of a copy of the original patent is useful for the calculation of the reissue filing fee and for the verification of other identifying data." M.P.E.P., § 1416, 7th ed.

NOTE: "If a reissue be refused, the original patent will be returned to applicant upon his request." 37 C.F.R. § 1.178.

(Reissue Application Transmittal [17-1]—page 2 of 6)

663727-01343460

6. Petition to proceed without assignee's assent

☐ Attached hereto is a "PETITION TO PROCEED WITH REISSUE APPLICATION WITHOUT ASSIGNEE'S ASSENT".

A. ☐ The fee payment is authorized in the attached:

☐ "REISSUE APPLICATION TRANSMITTAL" Form

☐ "COMPLETION OF FILING REQUIREMENTS — REISSUE APPLICATION" Form.

B. ☐ Payment is authorized below.

7. Information Disclosure Statement

☒ Attached

☐ Copies of the IDS citation(s) is/are attached.

8. Priority—35 U.S.C. § 119

☐ Priority of application Application No. 0 / _____, filed on _____, in _____ is claimed under 35 U.S.C. § 119.
Country

☐ The certified copy has been filed in prior application Application No. 0 / _____ filed on _____

9. Basic Filing Fee Calculation (37 C.F.R. § 1.16(h), (i) and (j))

CLAIMS AS FILED			
Number Filed	Number Extra	Rate	Basic Fee (37 C.F.R. 1.16(h)) \$760.00
Total Claims (37 C.F.R. § 1.16(i))	32 — 20 (and also in excess of total claims in patent)	12X \$18.00	216.00
Independent Claims 37 C.F.R. § 1.16(i))	5 — (number of inde- pendent claims in patent) (3)=2X	\$78.00	156.00
Filing fee Calculation			\$ 1,132.00

NOTE: Multiple dependent claims are treated as ordinary claims for fee purposes. 37 C.F.R. § 1.16(j).

(Reissue Application Transmittal [17-1]—page 3 of 6)

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10. Small Entity Status (if applicable)

NOTE: A new statement is required for the reissue, even if one has been filed in the original patent. 37 C.F.R. § 1.27(a).

WARNING: "Small entity status must not be established when the person or persons signing the . . . statement can *unequivocally* make the required self-certification." M.P.E.P. § 509.03, 6th ed., rev. 2, July 1996 (emphasis added).

- ☐ A statement that this filing is by a small entity is
☐ attached.

Filing Fee Calculation (50% of above) \$ _____

NOTE: If a statement is filed within 2 months of the date of timely payment of a fee, then the excess fee paid will be refunded on request. 37 C.F.R. § 1.28(a). Effective April 1, 1984.

11. Additional Fee Payments

- ☐ Payment is being made for "PETITION TO PROCEED WITH REISSUE APPLICATION WITHOUT ASSIGNEE"
(37 C.F.R. § 1.17(h)) \$130.00

12. Total Fees Due

Filing Fee	\$ 1,132.00
Petition fee	\$ _____
Total Fees Due	\$ 1,132.00

13. Method Of Payment of Fees

- ☒ Enclosed is a check in the amount of \$ 1,132.00
☐ Charge Account No. _____ in the amount of \$ _____
A duplicate of this request is attached.

NOTE: Fees should be itemized in such a manner that it is clear for which purpose the fees are paid. 37 C.F.R. § 1.22(b).

Please charge or credit our Deposit Account No. 08-2461
for any deficiency or overpayment. A duplicate of this
request is attached.

14. Authorization To Charge Additional Fees

WARNING: If no fees are to be paid on filing, the following items should not be completed.

WARNING: Accurately count claims, especially multiple dependent claims, to avoid unexpected high charges, if extra claim charges are authorized.

☒ The Commissioner is hereby authorized to charge the following additional fees by this paper and during the entire pendency of this application to Account No. 08-2461 :

☒ 37 C.F.R. § 1.16(a), (f) or (g) (filing fees)

☒ 37 C.F.R. § 1.16(b), (c) and (d) (presentation of extra claims)

NOTE: Because additional fees for excess or multiple dependent claims not paid on filing or on later presentation must only be paid or these claims cancelled by amendment prior to the expiration of the time period set for response by the PTO in any notice of fee deficiency (37 C.F.R. § 1.16(d)), it might be best not to authorize the PTO to charge additional claim fees, except possibly when dealing with amendments after final action.

☒ 37 C.F.R. § 1.16(e) (surcharge for filing the basic filing fee and/or declaration on a date later than the filing date of the application)

☐ 37 C.F.R. § 1.17(a)(1)-(5) (extension fees pursuant to § 1.136(a)).

☒ 37 C.F.R. § 1.17 (application processing fees)

NOTE: "A written request may be submitted in an application that is an authorization to treat any concurrent or future reply, requiring a petition for an extension of time under this paragraph for its timely submission, as incorporating a petition for extension of time for the appropriate length of time. An authorization to charge all required fees, fees under § 1.17, or all required extension of time fees will be treated as a constructive petition for an extension of time in any concurrent or future reply requiring a petition for an extension of time under this paragraph for its timely submission. Submission of the fee set forth in § 1.17(a) will also be treated as a constructive petition for an extension of time in any concurrent reply requiring a petition for an extension of time under this paragraph for its timely submission." 37 C.F.R. § 1.136(a)(3).

NOTE: "Amounts of twenty-five dollars or less will not be returned unless specifically requested within a reasonable time, nor will the payer be notified of such amounts; amounts over twenty-five dollars may be returned by check or, if requested, by credit to a deposit account." 37 C.F.R. § 1.26(a).

☐ 37 C.F.R. § 1.18 (issue fee at or before mailing of Notice of Allowance, pursuant to 37 C.F.R. § 1.311(b))

NOTE: Where an authorization to charge the issue fee to a deposit account has been filed before the mailing of a Notice of Allowance, the issue fee will be automatically charged to the deposit account at the time of mailing the notice of allowance. 37 C.F.R. § 1.311(b).

NOTE: See 37 C.F.R. § 1.28.


15. ☒ Additional Enclosures

Reissue Declaration

Reg. No.: 30,152

Tel. No.: (973) 331-1700

Customer No.:


SIGNATURE OF PRACTITIONER
Salvatore J. Abbruzzese
(type or print name of practitioner)
Hoffmann & Baron, LLP
6900 Jericho Turnpike
P.O. Address
Syosset, NY 11791

Practitioner's Docket No. 498-53 CON/RES**PATENT****IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

In re application of: *Peter J. Schmitt; Jose F. Nunez

Application No.: / Group No.:

Filed:

For: THINLY WOVEN FLEXIBLE Examiner:

5,697,970 GRAFT* Issue Date: December 16, 1997

Patent*:

Issue Date: _____

Reexamination No.:

Issue Date: _____

Reissue:

*NOTE: Insert name(s) of inventor(s) and title for patent.

Assistant Commissioner for Patents

Washington, D.C. 20231

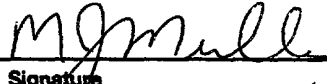
**STATEMENT UNDER 37 C.F.R. § 3.73(b)—
ESTABLISHING RIGHT OF ASSIGNEE TO TAKE ACTION****CERTIFICATION UNDER 37 C.F.R. §§ 1.8(a) and 1.10***
(When using Express Mail, the Express Mail label number is mandatory;
Express Mail certification is optional.)

I hereby certify that, on the date shown below, this correspondence is being:

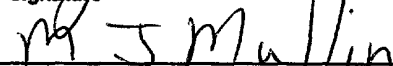
MAILING☒ deposited with the United States Postal Service in an envelope addressed to the Assistant Commissioner for Patents, Washington, D.C. 20231

37 C.F.R. § 1.8(a)

37 C.F.R. § 1.10*

☐ with sufficient postage as first class mail.☒ as "Express Mail Post Office to Addressee"Mailing Label No. EJ29940144US(mandatory)**TRANSMISSION**☐ transmitted by facsimile to the Patent and Trademark Office.

Signature

Date: December 15, 1999

(type or print name of person certifying)

***WARNING:** Each paper or fee filed by Express Mail **must** have the number of the "Express Mail" mailing label placed thereon prior to mailing. 37 C.F.R. § 1.10(b)."Since the filing of correspondence under § 1.10 without the Express Mail mailing label thereon is an oversight that can be avoided by the exercise of reasonable care, requests for waiver of this requirement will **not** be granted on petition." Notice of Oct. 24, 1996, 60 Fed. Reg. 56,439, at 56,442.

NOTE: 37 CFR 3.73(b) states: "When an assignee seeks to take action in a matter before the Office with respect to a patent application, . . . , patent, registration, or reexamination proceeding, the assignee must establish its ownership of the property to the satisfaction of the Commissioner. Ownership is established by submitting to the Office, in the Office file related to the matter in which action is sought to be taken, documentary evidence of a chain of title from the original owner to the assignee (e.g., copy of an executed assignment submitted for recording) or by specifying (e.g., reel and frame number) where such evidence is recorded in the Office. The submission establishing ownership must be signed by a party authorized to act on behalf of the assignee. Documents submitted to establish ownership may be required to be recorded as a condition to permitting the assignee to take action in a matter pending before the Office."

NOTE: "Section 3.73(b) is amended to remove the sentence requiring an assignee to specifically state that the evidentiary documents have been reviewed and to certify that title is in the assignee seeking to take action. The sentence is deemed to be unnecessary in view of the amendment to §§ 1.4(d) and 10.18." Notice of Oct. 10, 1997, 62 Fed. Reg. 53,131, at 53,174.

1. The assignee(s) of the entire right, title and interest hereby seek(s) to take action in the PTO in this matter.

IDENTIFICATION OF ASSIGNEE

2. Meadox Medicals, Inc.
Name of assignee
Corporation
Type of assignee, e.g., corporation, partnership, university, government agency, etc.

PERSON AUTHORIZED TO SIGN

3. _____
(type name of person authorized to sign on behalf of assignee)

Title of person authorized to sign

NOTE: The Notice of April 30, 1993 (1150 O.G. 62-64) points out:

"The statement under 37 CFR 3.73(b) may be signed on behalf of the assignee in the following two manners if the assignee is an organization (e.g., corporation, partnership, university, government agency, etc.).

"(1) The statement may be signed by a person in the organization having apparent authority to sign on behalf of the organization. An officer (president, vice-president, secretary, or treasurer) is presumed to have authority to sign on behalf of the organization. The signature of the chairman of the board of directors is acceptable, but not the signature of an individual director. A person having a title (manager, director, administrator, general counsel) that does not clearly set forth that person as an officer of the assignee is not presumed to be an officer of the assignee or to have authority to sign the statement on behalf of the assignee. A power of attorney from the inventors in an organization to a practitioner to prosecute a patent application does not make the practitioner an official of an assignee or empower the practitioner to sign the statement on behalf of the assignee.

"(2) The statement may be signed by any person, if the statement includes an averment that the person is empowered to sign the statement on behalf of the assignee and, if not signed by a registered practitioner, the statement must be in oath or declaration form. Where a statement does not include such an averment, and the person signing does not hold a position in the organization that would give rise to a presumption that the person is empowered to sign the statement on behalf of the assignee, evidence of the person's authority to sign will be required."

[Author's Note: The requirement for an oath or declaration for this statement by a person not a registered practitioner was rescinded by the rules effective December 1, 1997.]

(complete the following, if applicable)

☐ I, the person signing below, state that I am empowered to sign this statement on behalf of the assignee.

(Statement under 37 C.F.R. § 3.73(b) — Establishing Right of Assignee to Take Action [16-16]—page 2 of 4)

BASIS OF ASSIGNEE'S INTEREST

Ownership by the assignee is established as follows:

A.

1. ☒ An assignment from the inventor(s) of the matter identified above, which was recorded in the PTO at
Reel 7111, Frame 0854.
2. ☐ An assignment (document) separately being submitted for recordal herewith.

AND/OR

- B.** ☒ A chain of title from the inventor(s) to the current assignee as shown below:

1. From: Peter J. Schmitt
Name of inventor(s)
To: Meadox Medicals, Inc.
Recorded in PTO: Reel 7111, Frame 0854
2. From: Jose F. Nunez
Name of inventor(s) or assignee
To: Meadox Medicals, Inc.
Recorded in PTO: Reel 7111, Frame 0854
3. From: _____
Name of inventor(s) or assignee
To: _____
Recorded in PTO: Reel _____, Frame _____

(check item below, and add details, if applicable)

- ☐ Additional documents in the chain of title are listed in the attached Supplemental Sheet.

COPIES OF DOCUMENTS IN CHAIN OF TITLE

(complete this item, if copies are being sent)

- ☒ Copies of the assignment(s) or other document(s) in the chain of title are attached as follows:

☒ A ☒ 1 ☐ 2
☒ B ☒ 1 ☒ 2 ☐ 3

553727-01349460

665427-07949450

Reg. No.: 30,152

Tel. No.: (973) 331-1700

Customer No.:

(Signature of authorized person)

(type or print name of authorized person)

Title of authorized person



SIGNATURE OF PRACTITIONER

Salvatore J. Abbruzese

(type or print name of practitioner)

Hoffmann & Baron, LLP

P.O. Address

6900 Jericho Turnpike
Syosset, NY 11791

(Statement under 37 C.F.R. § 3.73(b) — Establishing Right of Assignee to Take Action [16-16]—page 4 of 4)

Practitioner's Docket No. 498-53 CON/RES**PATENT****REISSUE APPLICATION BY THE INVENTOR, OFFER TO SURRENDER
(37 C.F.R. § 1.178)**

To the Assistant Commissioner for Patents:

1. The undersigned applicant of the accompanying reissue application for the reissue of letters patent for the improvement in THINLY WOVEN FLEXIBLE GRAFT
Patent number 5,697,970 granted to him/her on December 16, 1997, of which

- ☐ he/she is now sole owner,
☒ Meadox Medicals, Inc.

is now sole owner by assignment, and on whose behalf and with whose assent the accompanying application is made,

☒ The "ASSENT BY THE ASSIGNEE" to this reissue application is attached.

Date: 12-13-99

Signature(s)

Jose F. Nunez

(type or print name(s))

CERTIFICATION UNDER 37 C.F.R. § 1.10*
(Express Mail label number is mandatory.)
(Express Mail certification is optional.)

I hereby certify that this correspondence and the documents referred to as attached therein are being deposited with the United States Postal Service on this date December 15, 1999, in an envelope as "Express Mail Post Office to Addressee," service under 37 C.F.R. § 1.10, Mailing Label Number E.I.279940144US addressed to the: Assistant Commissioner for Patents, Washington, D.C. 20231.

M J Mullin
(type or print name of person mailing paper)M J Mullin
Signature of person mailing paper

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(Reissue Application by the Inventor, Offer to Surrender (37 C.F.R. § 1.178)—Assent of Assignee
[17-2]—page 1 of 2)

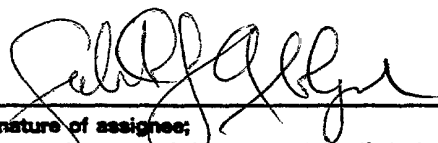
ASSENT OF ASSIGNEE TO REISSUE

The undersigned, assignee of the entire interest in the above-mentioned letters patent, hereby assents to the accompanying application.

STATEMENT BY ASSIGNEE

- ☒ Attached is a "STATEMENT UNDER 37 C.F.R. 3.73(b)," establishing the right of the assignee to take action in this reissue.

Date: Dec 15, 1999


Signature of assignee;
(type or print name of signatory and title if signing
on behalf of an entity)

Salvatore J. Abbruzzese

Reg. No. 30,152

Practitioner's Docket No. 498-53 CON/RES**PATENT****REISSUE APPLICATION BY THE INVENTOR, OFFER TO SURRENDER
(37 C.F.R. § 1.178)**

To the Assistant Commissioner for Patents:

1. The undersigned applicant of the accompanying reissue application for the reissue of letters patent for the improvement in THINLY WOVEN FLEXIBLE GRAFT
Patent number 5,697,970 granted to him/her on December 16, 1997, of which

- ☐ he/she is now sole owner,
☒ Meadox Medicals, Inc.

is now sole owner by assignment, and on whose behalf and with whose assent the accompanying application is made,

☒ The "ASSENT BY THE ASSIGNEE" to this reissue application is attached.

Date: December 8, 1999

Signature(s)

Peter J. Schmitt

(type or print name(s))

CERTIFICATION UNDER 37 C.F.R. § 1.10*
(Express Mail label number is mandatory.)
(Express Mail certification is optional.)

I hereby certify that this correspondence and the documents referred to as attached therein are being deposited with the United States Postal Service on this date December 15, 1999, in an envelope as "Express Mail Post Office to Addressee," service under 37 C.F.R. § 1.10, Mailing Label Number EJ279940144US, addressed to the: Assistant Commissioner for Patents, Washington, D.C. 20231.

M J Mullin
(type or print name of person mailing paper)M J Mullin
Signature of person mailing paper

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(Reissue Application by the Inventor, Offer to Surrender (37 C.F.R. § 1.178)—Assent of Assignee
[17-2]—page 1 of 2)

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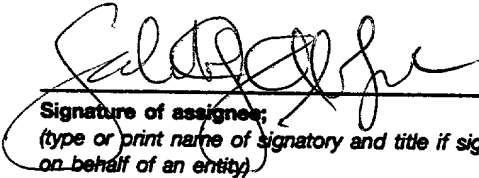
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Date: Dec 15, 1999


Signature of assignee;
(type or print name of signatory and title if signing
on behalf of an entity)

Salvatore J. Abbruzzese

Reg. No. 30,152

THINLY WOVEN FLEXIBLE GRAFT

This is a continuation of application(s) Ser. No. 08/285,334 filed on Aug. 2, 1994, abandoned May 21, 1996.

FIELD OF THE INVENTION

The present invention relates generally to synthetic tubular prostheses and more particularly the present invention relates to a flexible vascular graft formed of thinly woven textile material.

BACKGROUND OF THE INVENTION

Textile grafts are widely used to replace or repair damaged or diseased vessels of the body. Textile vascular grafts may be implanted in the vascular system for the repair of arteries and veins. Traditionally, graft implantation is conducted in a surgical procedure requiring the body to be opened adjacent to the implantation site. Improvements in medical procedures now additionally permit graft implantation to be done in a less invasive manner. Vascular endoscopic surgery permits certain grafts to be implanted with a hollow catheter delivery system. The catheter enters the vessel either percutaneously or through a small incision. The catheter delivery system passes the graft through the lumen of the blood vessel for deployment at the desired location. In order to minimize trauma at the site of insertion of the catheter, it is desirable to employ the smallest diameter catheter possible. Accordingly, a graft which is to be implanted by the catheter delivery system would also have to be as thin as possible so that it can be radially compressed and packed inside the lumen of a hollow catheter for deployment in the blood vessel. As the size of the graft dictates the size of the catheter employed, providing a thin graft allows use of a small diameter catheter and therefore results in less trauma during implantation.

Traditional grafts currently available, having a wall thickness of 0.25 to 0.75 mm, are designed for surgical implantation and would not lend themselves to successful catheter delivery. Also, since catheter delivery is typically done under a fluoroscope or other similar x-ray type viewing mechanism, the movement of traditional textile vascular grafts during deployment cannot be fluoroscopically viewed. Further, as with traditional surgically implanted grafts, catheter implanted grafts must be longitudinally flexible to conform to the shape of the vessel which it is repairing. Also, such grafts should be capable of a certain degree of longitudinal expansion to conform to the length of the blood vessel which is to be replaced. Finally, the graft, once implanted by the catheter delivery system, must readily return to its open tubular shape and maintain that shape during use. This is particularly important where the graft is implanted by a catheter as the graft must be tightly compressed and packed so as to fit within the hollow lumen of the catheter.

In order to maintain the desired flexibility, longitudinal expansion and a certain degree of radial structural integrity, it is known to provide pleated, wave-like corrugations or crimps along the length of a textile vascular graft. These crimps provide flexibility to the graft and the ability for the graft to longitudinally expand in a spring-like manner.

An example of a traditional surgically implanted graft having wave-like crimps or corrugations to provide flexibility, stretch and radially support is shown in U.S. Pat. No. 3,142,067. As can be seen in the '067 patent, these wave-like crimps or corrugations have a relatively large amplitude so as to impart the desired degree of flexibility.

stretch and structural integrity to the graft. Such large crimps in the wall of the graft presents an irregular profile of the graft wall with a relatively large difference between the major and minor diameter thereof. This area is susceptible to thrombus and plaque formation and build-up which is undesirable in a vascular graft.

It is therefore desirable to provide an improved thinly woven textile graft which exhibits sufficient spring-like elasticity and flexibility and which may be compressed in a manner which permits catheter implantation into a blood vessel.

SUMMARY OF THE INVENTION

It is an object of the present invention to provide a thinly woven textile prosthetic implant capable of being catheter implanted into a body lumen.

It is a further object of the present invention to provide a thinly woven textile graft having a fabric thickness not exceeding about 0.16 mm and having a pattern of fine crimps therealong.

It is a still further object of the present invention to provide a thinly woven textile graft having a pattern of finely spaced wave-like crimps therealong wherein the peak-to-peak amplitude of the wave-like crimps does not exceed 0.5 mm.

In the efficient attainment of these and other objects, the present invention provides a woven textile prosthetic implant including an elongate tubular body formed of a woven fabric having a fabric thickness which is no greater than about 0.16 mm. The tubular body includes a series of longitudinally spaced wave-like generally uniform crimps along the length thereof. The crimps have a crimp frequency of no less than about 6 crimps per centimeter of body length.

As further described by way of the preferred embodiment herein, the wave-like generally uniform crimps include a peak-to-peak amplitude which is no greater than about 0.5 mm. This reduces the area in which thrombus formation may take place.

Additionally, the present invention specifically provides an intraluminally implantable graft having a wall thickness sufficiently thin such that the graft may be radially compressed for insertion into a delivery catheter for catheter implantation.

BRIEF DESCRIPTION OF THE DRAWINGS

FIG. 1 shows schematically, in partial section, a conventionally formed prosthetic graft.

FIG. 2 shows schematically, in partial section, a prosthetic graft formed in accordance with the present invention.

FIG. 3 shows schematically, in partial section, the present invention embodied in a bifurcated design.

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENTS

The present invention provides an improved textile prosthetic implant. Specifically the preferred embodiment of the present invention is directed towards an implantable graft which is used to replace a damaged section of a body vessel such as a blood vessel. However, the present invention need not be limited thereto. A prosthetic implant in accordance with the present invention may be used intraluminally to support any diseased or otherwise damaged body vessel.

Referring to FIG. 1, a conventional vascular graft 10 is shown. Graft 10 is a textile product formed of a woven or

knitted synthetic fabric in a manner which is well known in the graft art. Graft 10 includes a generally tubular body 12 having opposed ends 14 and 16 which define therebetween an open lumen 18 which permits passage of blood once the graft 10 is implanted in the blood vessel. As graft 10 is designed to repair or replace a damaged or missing blood vessel, typically in a surgical procedure, the graft must be suitably pliable to adapt to the configuration of the vessel into which it is being implanted and also must be flexible enough to be handled and manipulated by the surgeon. As important, once the graft 10 is implanted, the graft must maintain a tubular configuration so that lumen 18 remains open allowing the passage of blood.

In order to enhance the pliability, ease of handling and structural stability of the tube, it has been known to provide tubular graft 10 with a series of wave-like crimps 20 along the body thereof. Crimps 20 follow a generally sinusoidal wave-like pattern continuously along the length of graft 10. Crimps 20 may be imparted to graft 10 in one of a number of well-known techniques. For instance, the uncrimped tubular graft may be compressed over a mandrel and then by an application of heat, the crimp pattern will take a set. Other techniques such as disposing graft 10 over a screw-threaded mandrel and heating the mandrel, may also impart a desired crimp-like pattern to the graft. Regardless of the technique used to form the wave-like crimps, the number and size of crimps on any particular graft is limited by the fabric or wall thickness of the graft. Where the wall thickness of the graft is relatively thick, say greater than 0.20 mm, successive crimps cannot be closely spaced. That is, the graft cannot have finely pitched crimps. Thus, it can be appreciated that the relative thickness of the fabric prevents the waves from being closely compacted. Accordingly in order to establish the longitudinal flexibility needed, as well as to impart sufficient tubular integrity, it is necessary to provide wave-like crimps having a relatively large amplitude. The amplitude of the wave, which is dictated by the thickness of the fabric, permits the graft to be longitudinally stretched so as to conform to the portion of the blood vessel which must be replaced or repaired. Further, such large amplitude crimps permit the graft to be easily flexed to permit ease of implantation and also provide a certain degree of structural stability to maintain the graft in an open tubular configuration.

However, when employing the graft as a vascular graft, the large amplitudes of the crimps have a tendency to promote the formation of thrombus and plaque build-up between the crimps which may be detrimental to the long-term patency of the graft. Further, the relatively large amplitude crimps provide a significantly more irregular profile of the graft wall which can undesirably increase the amount of turbulence created within the vessel.

Heretofore attempts to provide a graft with finer pitched crimps of lower amplitude have been found to be unacceptable for usage. Thick wall grafts having finer crimps and/or crimps of lower amplitude do not exhibit a sufficient pliancy, spring-like elasticity and structural integrity to be suitable for implantation.

Referring now to FIG. 2, the graft of the present invention may be described. Graft 30 is an elongate generally tubular member formed of woven synthetic fibers such as polyester. However it may be appreciated that other materials, as well as other forming techniques such as knitting may also be employed. Graft 30 includes a tubular body 32 having opposed ends 34 and 36 which define therebetween an open lumen 37. Graft 30 defines a generally tubular fabric wall 35 having a fabric thickness not exceeding about 0.16 mm.

An example of a graft formed in accordance with the present invention may be formed from a plain weave tubular fabric having a warp yarn of 50 denier, 48 filament flat polyester and weft yarn of 50 denier, 48 filament flat polyester. The ends per inch would be 188 per layer while the picks per inch would be 88 per layer. The fabric so formed would have a wall thickness of approximately 0.12 mm. After weaving into a tubular graft, the graft would be scoured to remove dirt, oil and other processing agents. The material may be then heat set to stabilize the graft. Heat setting can be accomplished in one of many conventionally known techniques such as heating in a steam autoclave or a conventional oven. The tubular fabric can also be heat set on smooth mandrels to precisely set the diameter and to remove any creases or wrinkles. As above described, the grafts may then be crimped to impart longitudinal compliance and radial support.

As the grafts of the present invention have a fabric wall thickness which is much thinner than grafts presently conventionally available, a finer crimp pattern may be imparted to graft 30 of the present invention. Crimp pattern 40 shown in FIG. 2 includes a series of wave-like crimps 38 therealong. Crimps 38 may be imparted on a finer pitch as the relatively thin fabric would not impede such fine pinch crimping.

It has been found that the maximum number of crimps that can be imparted to a tubular graft follows the equation:

$$C = [2(t - 10)]^{-1}$$

where C is the number of crimps per centimeter of length of the tube and t is the fabric or wall thickness of the graft.

Thus, a graft having a maximum fabric or wall thickness of 0.16 mm could be crimped to a pitch of about 33 crimps per centimeter. By permitting such a fine crimp pattern along the length of tubular graft 30, the amplitude of the crimps can be reduced without significantly reducing the longitudinal flexibility or structural stability of the graft. It has been found that forming a graft in accordance with the present invention, the amplitude, measured peak-to-peak, of the wave-like crimp pattern can be reduced to no greater than 0.5 mm. A crimp pattern having such a small amplitude greatly reduces risk of thrombus or plaque formation on the interior of the graft.

The thinly woven graft of the present invention may be radially compressed for insertion within the lumen of the catheter (not shown) for catheter implantation within a body vessel. The thin construction of the graft of the present invention permits such catheter implantation. The above described example permits use of a small diameter endoluminal catheter which tends to reduce trauma at the insertion site. In the preferred example describe above, catheters such as an 8 cm long balloon, PE-MT balloon angioplasty catheter manufactured by Meditech-Boston Scientific, Inc. or a 10 mm diameter by 4 cm long OLBERT® balloon catheter manufactured by Meadox Surgimed A/S may be employed for introducing and implanting graft 30.

Once deployed, the graft 30 must maintain its longitudinal flexibility as well as return to its tubular open lumen configuration. The particular pattern of crimps employed with the present invention permits such longitudinal flexibility and structural integrity without increasing the graft thickness as measured both by fabric wall thickness and as measured between the peak-to-peak amplitude of the wave-like pattern of crimps.

In addition, as graft 30 is designed to be catheter implanted it is generally desirable to provide means for

09464610 " 1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23 24 25 26 27 28 29 30 31 32 33 34 35 36 37 38 39 40 41 42 43 44 45 46 47 48 49 50 51 52 53 54 55 56 57 58 59 60 61 62 63 64 65 66 67 68 69 70 71 72 73 74 75 76 77 78 79 80 81 82 83 84 85 86 87 88 89 90 91 92 93 94 95 96 97 98 99 100 101 102 103 104 105 106 107 108 109 110 111 112 113 114 115 116 117 118 119 120 121 122 123 124 125 126 127 128 129 130 131 132 133 134 135 136 137 138 139 140 141 142 143 144 145 146 147 148 149 150 151 152 153 154 155 156 157 158 159 160 161 162 163 164 165 166 167 168 169 170 171 172 173 174 175 176 177 178 179 180 181 182 183 184 185 186 187 188 189 190 191 192 193 194 195 196 197 198 199 200 201 202 203 204 205 206 207 208 209 210 211 212 213 214 215 216 217 218 219 220 221 222 223 224 225 226 227 228 229 230 231 232 233 234 235 236 237 238 239 240 241 242 243 244 245 246 247 248 249 250 251 252 253 254 255 256 257 258 259 260 261 262 263 264 265 266 267 268 269 270 271 272 273 274 275 276 277 278 279 280 281 282 283 284 285 286 287 288 289 290 291 292 293 294 295 296 297 298 299 300 301 302 303 304 305 306 307 308 309 310 311 312 313 314 315 316 317 318 319 320 321 322 323 324 325 326 327 328 329 330 331 332 333 334 335 336 337 338 339 340 341 342 343 344 345 346 347 348 349 350 351 352 353 354 355 356 357 358 359 360 361 362 363 364 365 366 367 368 369 370 371 372 373 374 375 376 377 378 379 380 381 382 383 384 385 386 387 388 389 390 391 392 393 394 395 396 397 398 399 400 401 402 403 404 405 406 407 408 409 410 411 412 413 414 415 416 417 418 419 420 421 422 423 424 425 426 427 428 429 430 431 432 433 434 435 436 437 438 439 440 441 442 443 444 445 446 447 448 449 450 451 452 453 454 455 456 457 458 459 460 461 462 463 464 465 466 467 468 469 470 471 472 473 474 475 476 477 478 479 480 481 482 483 484 485 486 487 488 489 490 491 492 493 494 495 496 497 498 499 500 501 502 503 504 505 506 507 508 509 510 511 512 513 514 515 516 517 518 519 520 521 522 523 524 525 526 527 528 529 530 531 532 533 534 535 536 537 538 539 540 541 542 543 544 545 546 547 548 549 550 551 552 553 554 555 556 557 558 559 560 561 562 563 564 565 566 567 568 569 570 571 572 573 574 575 576 577 578 579 580 581 582 583 584 585 586 587 588 589 590 591 592 593 594 595 596 597 598 599 600 601 602 603 604 605 606 607 608 609 610 611 612 613 614 615 616 617 618 619 620 621 622 623 624 625 626 627 628 629 630 631 632 633 634 635 636 637 638 639 640 641 642 643 644 645 646 647 648 649 650 651 652 653 654 655 656 657 658 659 660 661 662 663 664 665 666 667 668 669 670 671 672 673 674 675 676 677 678 679 680 681 682 683 684 685 686 687 688 689 690 691 692 693 694 695 696 697 698 699 700 701 702 703 704 705 706 707 708 709 710 711 712 713 714 715 716 717 718 719 720 721 722 723 724 725 726 727 728 729 730 731 732 733 734 735 736 737 738 739 740 741 742 743 744 745 746 747 748 749 750 751 752 753 754 755 756 757 758 759 760 761 762 763 764 765 766 767 768 769 770 771 772 773 774 775 776 777 778 779 780 781 782 783 784 785 786 787 788 789 790 791 792 793 794 795 796 797 798 799 800 801 802 803 804 805 806 807 808 809 810 811 812 813 814 815 816 817 818 819 820 821 822 823 824 825 826 827 828 829 830 831 832 833 834 835 836 837 838 839 840 841 842 843 844 845 846 847 848 849 850 851 852 853 854 855 856 857 858 859 860 861 862 863 864 865 866 867 868 869 870 871 872 873 874 875 876 877 878 879 880 881 882 883 884 885 886 887 888 889 890 891 892 893 894 895 896 897 898 899 900 901 902 903 904 905 906 907 908 909 910 911 912 913 914 915 916 917 918 919 920 921 922 923 924 925 926 927 928 929 930 931 932 933 934 935 936 937 938 939 940 941 942 943 944 945 946 947 948 949 950 951 952 953 954 955 956 957 958 959 960 961 962 963 964 965 966 967 968 969 970 971 972 973 974 975 976 977 978 979 980 981 982 983 984 985 986 987 988 989 990 991 992 993 994 995 996 997 998 999 1000

viewing the implanted graft fluoroscopically. Graft 30 may include a radiopaque guideline or marker. As shown in FIG. 2, marker 45 may extend the length of graft 30. Other patterns for marker 45 may also be employed. Radiopaque marker 45 assists the surgeon to visualize the graft both during and after implantation. The marker 45 would help show the surgeon that the graft is properly positioned. Also, it will indicate whether the graft has dilated or collapsed after implantation. Further, during endoscopic implantation, marker 45 may be used to assist in the proper positioning of the graft.

As is well known, radiopaque guidelines or markers may be formed from metallic fibers such as stainless steel or titanium. Also, one or more polymeric fibers may be coated or filled with radiopaque particles.

The present invention is not limited to the graft shape show in FIG. 2. other graft configurations are within the contemplation thereof. For example, referring to FIG. 3, a bifurcated graft 50, may also be formed in accordance with the present invention. Graft 50 is an elongate generally tubular member having a first end 54 having a single lumen extending therefrom. An opposed end 56 is bifurcated into a pair of smaller tubular members 56a and 56b. A graft of this type may be used to repair and replace a main vessel and branch vessels. In accordance with the present invention graft 50 is crimped in a manner described above to impart longitudinal flexibility, structural integrity and spring-like compliance.

Various changes to the foregoing described and shown structures would now be evident to those skilled in the art. Accordingly, the particularly disclosed scope of the invention is set forth in the following claims.

What is claimed is:

1. A woven textile prosthetic implant comprising:
an elongate tubular body formed of a fabric wall having³⁵
a fabric wall thickness no greater than about 0.16 mm.
said tubular body having longitudinally spaced wave-
like, generally uniform crimps along the length thereof.
said crimps extending on both sides of said tubular
body and having a crimp frequency of no less than⁴⁰
about 6 crimps per centimeter.
2. A woven textile prosthetic implant of claim 1 wherein
said tubular body includes an x-ray detectable, radiopaque
yarn therein.
3. A woven textile prosthetic implant of claim 2 wherein⁴⁵
said radiopaque yarn extends longitudinally along the length
of the tubular body.
4. A woven textile prosthetic implant of claim 1 wherein
said wave-like crimps have a peak-to-peak amplitude of no
greater than about 0.5 mm.

5. A woven textile prosthetic implant of claim 1 wherein said body has a fabric thickness of about 0.12 mm and a maximum crimp frequency of about 42 crimps per cm.

6. A woven textile graft comprising:

- 5 an elongate tubular graft body having a wall, said wall having a thickness of no greater than about 0.16 mm and defining a pattern of wave-like crimps extending along both sides of said tubular body, the number of crimps, C, per centimeter of body length being defined by an equation:

$$C=[2(t \rightarrow 10)]^{-1};$$

- 15 wherein t equals the body wall thickness in mm.

7. A woven textile graft of claim 6 wherein said wave-like crimps define a peak-to-peak amplitude of no greater than about 0.5 mm.

8. A woven textile graft of claim 7 wherein said tubular body includes a radiopaque marker therein.

9. A woven textile graft of claim 8 wherein said marker extends the length of said tubular body.

10. A woven textile graft of claim 1 wherein said tubular body is bifurcated.

11. A woven textile intraluminally implantable graft comprising:

- 30 an elongate tubular graft body having a wall, said wall having a thickness of dimension such that the graft body is capable of being radially compressed for insertion into a delivery catheter;

35 said tubular graft body having a plurality of longitudinally spaced wave-like crimps along the length thereof on both sides of said tubular body, said wave-like crimps defining a crimp frequency of no less than 8 crimps per cm.

12. A woven textile graft of claim 11 wherein said wall thickness is no greater than about 0.16 mm.

13. A woven textile graft of claim 12 wherein said crimps have a generally uniform peak-to-peak amplitude not exceeding about 0.5 mm.

14. A woven textile graft of claim 13 wherein said tubular body includes a radiopaque marker therein.

15. A woven textile graft of claim 11 wherein said tubular body may be compressed for insertion into an endoluminal catheter.

16. A woven textile graft of claim 11 wherein said tubular graft body is bifurcated.

* * * * *

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17. A textile prosthetic implant comprising:
an elongate body formed from yarns woven into a tubular configuration, said
woven yarns defining a fabric wall having a thickness not exceeding about 0.16 mm.
18. A textile implant of claim 17 wherein said body is formed from a plain weave tubular
fabric.
19. A textile implant of claim 18 wherein said plain weave fabric includes a warp yarn, a weft
yarn.
20. A textile implant of claim 18 wherein said plain warp yarn and said weft yarn having
subsequent equal denier.
21. A textile implant of claim 18 wherein said warp yarn and said weft yarn are multifilament
yarns having approved equal number of filaments.
22. A textile implant of claim 18 wherein said warp yarn and said weft yarn are 50 denier, 48
filament flat polyester.
23. A textile implant of claim 17 wherein said fabric wall includes 17 ends per layer per inch
and 88 picks per layer per inch.

24. A textile implant of claim 17 wherein said fabric wall has a wall thickness of approximately 0.12 mm.
25. A textile implant of claim 17 wherein said body includes a plurality of longitudinally spaced wave-like crimps extending therealong.
26. A textile implant of claim 25 wherein said crimps have a uniform frequency therealong.
27. A textile implant of claim 25 wherein said crimp-frequency is no less than about 6 crimps per centimeter.
28. A textile graft comprising:
an elongate woven tubular body having a fabric wall of thickness not exceeding 0.16 mm;
said graft being radially compressible for catheter delivery and returnable to an open tubular configuration upon deployment.
29. A graft of claim 28 wherein said fabric wall thickness is approximately 0.12 mm.
30. A graft of claim 29 further including means for effecting said return of said graft to said open tubular configuration upon said deployment.
31. A graft of claim 30 wherein said effecting means includes said graft having a plurality of longitudinally spaced wave like crimps therealong.

32. A graft of claim 31 wherein said crimps have a uniform crimp frequency of about 6 crimps per centimeter.

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ABSTRACT

16 Claims, 2 Drawing Sheets

16 Claims, 2 Drawing Sheets

Practitioner's Docket No. 498-53 CON/RES**PATENT****REISSUE APPLICATION DECLARATION AND POWER OF ATTORNEY
(BY INVENTOR(S) OR ASSIGNEE)**

(complete A or B)

A. ☒ DECLARATION BY THE INVENTOR(S)

As a below named inventor, I hereby declare that:

My residence, post office address and citizenship are as stated below next to my name, I believe I am the original, first and sole inventor (*if only one name is listed below*) or an original, first and joint inventor (*if plural names are listed below*) of the subject matter that is described and claimed in letters patent number 5,697,970, granted on December 16, 1997, and for which invention I solicit a reissue patent on the invention entitled THINLY WOVEN FLEXIBLE GRAFT

the specification of which

☒ is attached hereto.☐ was filed on _____, as reissue application number / and was amended on _____ (*if applicable*).☐ I hereby declare that there is no assignee for this application.

NOTE: "Where no assignee exists, applicant should affirmatively state that fact. If the file record is silent as to the existence of an assignee, it will be presumed that no assignee exists." M.P.E.P., 6th ed., rev. 1, § 1410.01.

B. ☐ DECLARATION BY ASSIGNEE

NOTE: The assignee of the entire interest may make the declaration, if the reissue application does not seek to enlarge the scope of the claims of the original patent. 37 C.F.R. § 1.172.

(type or print name of declarant)_____
Title

of _____,

Name of company or legal entity on whose behalf declarant is authorized to sign

declare that I am a citizen of _____ and resident of _____,

_____, that the entire title to letters patent number _____,

for _____,

granted on _____, 19____ to _____

Inventor(s)

is vested in _____

Name of company or legal entity

that I believe said named inventor(s) to be an original, first and sole inventor (*if only one name is listed*) or an original, first and part inventor (*if plural names are listed*) of the subject matter that is described and claimed in the aforesaid letters patent and in the foregoing specification and for which invention I solicit a reissue patent.

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ACKNOWLEDGEMENT OF REVIEW OF PAPERS AND DUTY OF CANDOR

(37 C.F.R. § 1.175)

I hereby state that I have reviewed and understand the contents of the above identified specification, including the claims, as amended by any amendment referred to above.

I acknowledge the duty to disclose information that is material to patentability as defined in Title 37, Code of Federal Regulations, § 1.56.

☒ In compliance with this duty, there is attached an information disclosure statement in accordance with 37 C.F.R. § 1.98.

PRIORITY CLAIM

NOTE: A "claim" for the benefit of an earlier filing date in a foreign country under 35 U.S.C. 119(a)-(d) must be made in a reissue application even though such a claim was made in the application on which the original was granted. However, no additional certified copy of the foreign application is necessary. M.P.E.P., 6th ed., rev. 1, § 1417.

I hereby claim foreign priority benefits under Title 35, United States Code, § 119 of any foreign application(s) for patent or inventor's certificate listed below and have also identified below any foreign application for patent or inventor's certificate having a filing date before that of the application on which priority is claimed.

(complete C or D)

C. ☒ No such applications have been filed.

D. ☐ Such applications have been filed as follows:

**EARLIEST FOREIGN APPLICATION(S), IF ANY FILED WITHIN 12 MONTHS
(6 MONTHS FOR DESIGN) PRIOR TO SAID APPLICATION**

Country	Application No.	Date of filing (day, month, year)	Date of issue (day, month, year)	Priority Claimed
				<input type="checkbox"/> YES NO <input type="checkbox"/>
				<input type="checkbox"/> YES NO <input type="checkbox"/>
				<input type="checkbox"/> YES NO <input type="checkbox"/>

**ALL FOREIGN APPLICATION(S), IF ANY FILED MORE THAN 12 MONTHS
(6 MONTHS FOR DESIGN) PRIOR TO SAID APPLICATION**

BENEFIT OF PROVISIONAL APPLICATION

(Reissue Application Declaration and Power of Attorney [17-6]—page 2 of 6)

**STATEMENT OF INOPERATIVENESS
OR INVALIDITY OF ORIGINAL PATENT**

(37 C.F.R. § 1.175)

That I believe the original patent to be

☒ partly☐ wholly

inoperative or invalid by reason of (37 C.F.R. § 1.175(a)(1)):

(check all items that may apply)☐ a defective specification☐ a defective drawing☒ the patentee claiming more or less than the patentee had a right to claim in the patent.*NOTE: At least one error must be relied upon as the basis for the reissue. 37 C.F.R. § 1.175(a)(1).*

That the error listed above, which are being corrected, up to the time of the filing of this reissue declaration arose without any deceptive intention on the part of the applicant. (37 C.F.R. § 1.175(a)(2).

NOTE: For any error corrected not covered by this declaration applicant must submit, before allowance, a supplemental declaration stating that every such error arose without any deceptive intention on the part of the applicant. 37 C.F.R. § 1.175(b)(1).☐ Corroborating affidavits or declarations of others accompany this declaration.

POWER OF ATTORNEY

I hereby appoint the following practitioner(s) to prosecute this application and transact all business in the Patent and Trademark Office connected therewith.

(list name and registration number)

Charles R. Hoffmann, Reg. No. 24,102; Ronald J. Baron, Reg. No. 29,281; Gerald T. Bodner, Reg. No. 30,449; Alan M. Sack, Reg. No. 31,874; A. Thomas Kammer, Reg. No. 28,226; R. Glenn Schroeder, Reg. No. 34,720; Glenn T. Henneberger, Reg. No. 36,074; Irving N. Feit, Reg. No. 28,601; Anthony E. Bennett, Reg. No. 40,910; Gregory A. Bachmann, Reg. No. P41,593; Steven T. Zuschlag, Reg. No. 43,309; Susan A. Sipos, Reg. No. 43,128; and Kevin E. McDermott, Reg. No. 35,946, each of them of HOFFMANN & BARON, LLP, 6900 Jericho Turnpike, Syosset, New York 11791; and Daniel A. Scola, Jr., Reg. No. 29,855; Salvatore J. Abbruzzese, Reg. No. 30,152; Kirk M. Miles, Reg. No. 37,891; Robert F. Chisholm, Reg. No. 39,939; Kellyanne Merkel, Reg. No. 43,800; John S. Sopko, Reg. No. 41,321; Barry H. Jacobsen, Reg. No. 43,689; and Keith R. Lange, Reg. No. 44,201, and Gloria K. Szakiel, Reg. No. 45,149, each of them of HOFFMANN & BARON, LLP, 1055 Parsippany Boulevard, Parsippany, New Jersey 07054.

SEND CORRESPONDENCE TO

☒ Address

Hoffmann & Baron, LLP
6900 Jericho Turnpike
Syosset, NY 11791

☐ Customer Number _____

DIRECT TELEPHONE CALLS TO:

(Name and telephone number)

Salvatore J. Abbruzzese
(973) 331-1700

(Reissue Application Declaration and Power of Attorney [17-6]—page 4 of 6)

DECLARATION

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code, and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

Signature(s)☐ **BY THE INVENTOR(S)**Full name of sole or first inventor Peter J. Schmitt

Inventor's signature _____

Date _____ Country of Citizenship U.S.Residence 2 Bubenko Drive, Garnerville, NY 10923Post Office Address Same as aboveFull name of second joint inventor, if any Jose F. NunezInventor's signature Jose F. NunezDate 12/13/99 Country of Citizenship U.S.Residence 2804 Silver Lane, St. Anthony, MN 55421Post Office Address Same as above☐ **BY ASSIGNEE OR PERSON AUTHORIZED TO SIGN ON BEHALF OF ASSIGNEE**

NOTE: Even though inventor(s) do not sign, complete above information for inventor(s).

(complete the following, if applicable)

Meadox Medicals, Inc.
(type name of assignee)45 Barbour Pond Drive
Address of assigneeWayne, NJ 07470

Title of person authorized to sign on behalf of assignee

☒ Assignment recorded in PTO on 8/2/94Reel 7115Frame 0854

☒ A separate ☒ "ASSIGNMENT (DOCUMENT) COVER SHEET"
or ☐ FORM PTO 1595 is submitted herewith along with the assign-
ment _____

STATEMENT BY ASSIGNEE

- ☒ Attached is a "STATEMENT UNDER 37 C.F.R. 3.73(b)," establishing the right of the assignee to take action in this reissue.

Signature of assignee or person authorized to
sign on behalf of assignee

(check proper box(es) for any added page(s) forming a part of this declaration)

- ☐ Signature for third and subsequent joint inventors. Number of pages added. _____
- ☐ Signature by administrator(trix), executor(trix) or legal representative for deceased or incapacitated inventor. Number of pages added. _____
- ☐ Signature for inventor who refuses to sign or cannot be reached by person authorized under 37 C.F.R. § 1.47. Number of pages added. _____
- ☐ Statement of inoperativeness or invalidity of original patent. 37 C.F.R. § 1.175. Number of pages added _____
- ☐ Authorization of attorney(s) to accept and follow instructions from representative.
- ☐ Corroborating statements of others.

(Reissue Application Declaration and Power of Attorney [17-6]—page 6 of 6)

Practitioner's Docket No. 498-53 CON/RES**PATENT****REISSUE APPLICATION DECLARATION AND POWER OF ATTORNEY
(BY INVENTOR(S) OR ASSIGNEE)**

(complete A or B)

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the specification of which

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(type or print name of declarant)_____
Title

of _____,

Name of company or legal entity on whose behalf declarant is authorized to sign

declare that I am a citizen of _____ and resident of _____,

_____, that the entire title to letters patent number _____,

for _____,

granted on _____, 19____ to _____

Inventor(s)

is vested in _____

Name of company or legal entity

that I believe said named inventor(s) to be an original, first and sole inventor (*if only one name is listed*) or an original, first and part inventor (*if plural names are listed*) of the subject matter that is described and claimed in the aforesaid letters patent and in the foregoing specification and for which invention I solicit a reissue patent.

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(complete C or D)

- C. ☒ No such applications have been filed.
D. ☐ Such applications have been filed as follows:

**EARLIEST FOREIGN APPLICATION(S), IF ANY FILED WITHIN 12 MONTHS
(6 MONTHS FOR DESIGN) PRIOR TO SAID APPLICATION**

Country	Application No.	Date of filing (day, month, year)	Date of issue (day, month, year)	Priority Claimed
				<input type="checkbox"/> YES <input type="checkbox"/> NO
				<input type="checkbox"/> YES <input type="checkbox"/> NO
				<input type="checkbox"/> YES <input type="checkbox"/> NO

**ALL FOREIGN APPLICATION(S), IF ANY FILED MORE THAN 12 MONTHS
(6 MONTHS FOR DESIGN) PRIOR TO SAID APPLICATION**

BENEFIT OF PROVISIONAL APPLICATION

(Reissue Application Declaration and Power of Attorney [17-6]—page 2 of 6)

**STATEMENT OF INOPERATIVENESS
OR INVALIDITY OF ORIGINAL PATENT**
(37 C.F.R. § 1.175)

That I believe the original patent to be

☒ partly

☐ wholly

inoperative or invalid by reason of (37 C.F.R. § 1.175(a)(1)):

(check all items that may apply)

☐ a defective specification

☐ a defective drawing

☒ the patentee claiming more or less than the patentee had a right to claim in the patent.

NOTE: At least one error must be relied upon as the basis for the reissue. 37 C.F.R. § 1.175(a)(1).

That the error listed above, which are being corrected, up to the time of the filing of this reissue declaration arose without any deceptive intention on the part of the applicant. (37 C.F.R. § 1.175(a)(2).

NOTE: For any error corrected not covered by this declaration applicant must submit, before allowance, a supplemental declaration stating that every such error arose without any deceptive intention on the part of the applicant. 37 C.F.R. § 1.175(b)(1).

☐ Corroborating affidavits or declarations of others accompany this declaration.

POWER OF ATTORNEY

I hereby appoint the following practitioner(s) to prosecute this application and transact all business in the Patent and Trademark Office connected therewith.

(list name and registration number)

Charles R. Hoffmann, Reg. No. 24,102; Ronald J. Baron, Reg. No. 29,281; Gerald T. Bodner, Reg. No. 30,449; Alan M. Sack, Reg. No. 31,874; A. Thomas Kammer, Reg. No. 28,226; R. Glenn Schroeder, Reg. No. 34,720; Glenn T. Henneberger, Reg. No. 36,074; Irving N. Feit, Reg. No. 28,601; Anthony E. Bennett, Reg. No. 40,910; Gregory A. Bachmann, Reg. No. P41,593; Steven T. Zuschlag, Reg. No. 43,309; Susan A. Sipos, Reg. No. 43,128; and Kevin E. McDermott, Reg. No. 35,946, each of them of HOFFMANN & BARON, LLP, 6900 Jericho Turnpike, Syosset, New York 11791; and Daniel A. Scola, Jr., Reg. No. 29,855; Salvatore J. Abbruzzese, Reg. No. 30,152; Kirk M. Miles, Reg. No. 37,891; Robert F. Chisholm, Reg. No. 39,939; Kellyanne Merkel, Reg. No. 43,800; John S. Sopko, Reg. No. 41,321; Barry H. Jacobsen, Reg. No. 43,689; and Keith R. Lange, Reg. No. 44,201, and Gloria K. Szakiel, Reg. No. 45,149, each of them of HOFFMANN & BARON, LLP, 1055 Parsippany Boulevard, Parsippany, New Jersey 07054.

SEND CORRESPONDENCE TO

☒ Address

Hoffmann & Baron, LLP
6900 Jericho Turnpike
Syosset, NY 11791

☐ Customer Number _____

DIRECT TELEPHONE CALLS TO:

(Name and telephone number)

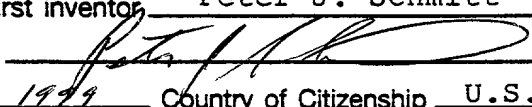
Salvatore J. Abbruzzese
(973) 331-1700

(Reissue Application Declaration and Power of Attorney [17-6]—page 4 of 6)

DECLARATION

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code, and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

Signature(s)☐ **BY THE INVENTOR(S)**

Full name of sole or first inventor Peter J. Schmitt
 Inventor's signature 
 Date December 8, 1994 Country of Citizenship U.S.
 Residence 2 Bubenko Drive, Garnerville, NY 10923
 Post Office Address Same as above

Full name of second joint inventor, if any Jose F. Nunez
 Inventor's signature _____
 Date _____ Country of Citizenship U.S.
 Residence 2804 Silver Lane, St. Anthony, MN 55421
 Post Office Address Same as above

☐ **BY ASSIGNEE OR PERSON AUTHORIZED TO SIGN ON BEHALF OF ASSIGNEE**

NOTE: Even though inventor(s) do not sign, complete above information for inventor(s).

(complete the following, if applicable)

Meadox Medicals, Inc.
 (type name of assignee)
45 Barbour Pond Drive
 Address of assignee
Wayne, NJ 07470

Title of person authorized to sign on behalf of assignee

☒ Assignment recorded in PTO on 8/2/94
 Reel 7115
 Frame 0854

☒ A separate ☒ "ASSIGNMENT (DOCUMENT) COVER SHEET"
 or ☐ FORM PTO 1595 is submitted herewith along with the assignment _____

STATEMENT BY ASSIGNEE

- ☒ Attached is a "STATEMENT UNDER 37 C.F.R. 3.73(b)," establishing the right of the assignee to take action in this reissue.

Signature of assignee or person authorized to
sign on behalf of assignee

(check proper box(es) for any added page(s) forming a part of this declaration)

- ☐ Signature for third and subsequent joint inventors. Number of pages added. _____
- ☐ Signature by administrator(trix), executor(trix) or legal representative for deceased or incapacitated inventor. Number of pages added. _____
- ☐ Signature for inventor who refuses to sign or cannot be reached by person authorized under 37 C.F.R. § 1.47. Number of pages added. _____
- ☐ Statement of inoperativeness or invalidity of original patent. 37 C.F.R. § 1.175. Number of pages added _____
- ☐ Authorization of attorney(s) to accept and follow instructions from representative.
- ☐ Corroborating statements of others.

(Reissue Application Declaration and Power of Attorney [17-6]—page 6 of 6)

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**In re application for Reissue of U.S. Patent No. 5,697,970**

Applicant(s): Schmitt, et al.

Examiner: Unassigned

Serial No.: Unassigned

Group Art Unit: 3308 (Anticipated)

Filed: Concurrently Herewith

Docket: 498-53 CON RES

For: THINLY WOVEN
FLEXIBLE GRAFT

Dated: December 15, 1999

Date 12/15/99 Label No. EJ279940144US

I hereby certify that on the date indicated above I deposited this paper or fee with the U.S. Postal Service and that it was addressed for delivery to the Assistant Commissioner of Patents, Washington, D.C. 20231 by "EXPRESS MAIL POST OFFICE to ADDRESSEE" service.

M. J. Mullin *M. J. Mullin*
Name (Print) (Signature)

Assistant Commissioner for Patents
Washington, DC 20231

REISSUE DECLARATION

Sir:

I, Jose F. Nunez, declare that I am a citizen of the United States and a resident of St. Anthony, Minnesota, and:

I, Peter J. Schmitt, declare that I am a citizen of the United States and a resident of Garnerville, New York, and:

that we believe that we are the original and first inventors of the subject matter claimed in U.S. Patent No. 5,697,970 (hereinafter the '970 patent), entitled "Thinly Woven Flexible Graft";

that we have reviewed and understand the specification of the accompanying reissue application, including the claims;

that we believe that we are the original and first inventors of the subject matter which is claimed and for which a reissue patent is sought; and

that we acknowledge our duty to disclose to the U.S. Patent and Trademark Office all information known to us to be material to patentability as defined in 37 C.F.R. §1.56.

We further declare that we believe the above-identified original patent to be partly

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inoperative or invalid by reason of our claiming less than we had a right to claim in the original patent. Specifically, we believe that the original patent is partly inoperative or invalid for including limitations in the claims that were not required by the prior art.

After reviewing the specification and issued claims of the U.S. Patent No. 5,697,970 and consulting with patent attorneys for Meadox Medicals, Inc. assignee of the '970 patent and the law firm of Hoffmann & Baron, LLP, who are outside patent counsel for Meadox, we came to the realization that we had inadvertently failed to claim certain broad aspects of our invention.

We believe that the error constituted inadvertent failure to appreciate the full scope of the claims which were available in view of the prior art, and that the error arose without any deceptive intent on our part.

Claim 17 of the reissue application corresponds generally with claim 1 of the '970 patent. Claim 17, however, differs from claim 1 in at least one respect including, for example:

the limitation "said tubular body having longitudinally spaced wave-like, generally uniform crimps along the length thereof, said crimps extending on both sides of the said tubular body and having a crimp frequency of no less than about 6 crimps per centimeter" included in claim 1 does not appear in claim 17.

This and other limitations in claim 1 and claim 11 resulted from the apparent failure of ourselves and patent counsel to fully appreciate the limiting nature of these claim limitations, as well as failure to fully appreciate the full scope of the invention as taught by the specification. During prosecution of the application, we did not fully realize or appreciate the effect of these limitations on the scope of coverage provided by this resulting patent.

We have always felt that a significant feature of this invention is that the prosthesis is a thinly woven structure, having a wall thickness not exceeding 0.16 mm. The thinly woven prosthesis of the present invention need not utilize a plurality of longitudinally spaced wave-like

crimps as set forth in the issued claims. Similarly, an aspect of the invention is the capability of the thinly woven graft to be radially compressed for insertion into a delivery catheter. We believe that the claims presented herewith enable the full scope of the invention to be appreciated.

Furthermore, all errors being corrected in the present reissue application arose without any deceptive intention on our part.

We declare that all statements made herein of our own knowledge are true, and that all statements made upon information and belief are believed to be true and further, that these statements were made after being warned that willful false statements and the like are punishable by fine or imprisonment, or both, under 18 U.S.C. §1001, and that such false statements may jeopardize the validity of this application or any patent issuing thereon.

Peter J. Schmitt


Inventor's Signature

December 10, 1999
Date

2 Bubenko Drive, Garnerville, NY 10923
Residence

Jose F. Nunez

Inventor's Signature

Date

2804 Silver Lane, Apt. 209, St. Anthony, MN 55421
Residence

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**In re application for Reissue of U.S. Patent No. 5,697,970**

Applicant(s): Schmitt, et al.

Examiner: Unassigned

Serial No.: Unassigned

Group Art Unit: 3308 (Anticipated)

Filed: Concurrently Herewith

Docket: 498-53 CON RES

For: THINLY WOVEN
FLEXIBLE GRAFT

Dated: December 15, 1999

Date 12/15/99 Label No. EJ279940144US

I hereby certify that on the date indicated above I
deposited this paper or fee with the U.S. Postal Service
and that it was addressed for delivery to the Assistant
Commissioner of Patents, Washington, D.C. 20231 by
"EXPRESS MAIL POST OFFICE to ADDRESSEE " service.

M.J. Mullin mjmullin
Name (Print) (Signature)

Assistant Commissioner for Patents
Washington, DC 20231

REISSUE DECLARATION

Sir:

I, Jose F. Nunez, declare that I am a citizen of the United States and a resident of St.
Anthony, Minnesota, and:

I, Peter J. Schmitt, declare that I am a citizen of the United States and a resident of
Garnerville, New York, and:

that we believe that we are the original and first inventors of the subject matter claimed in
U.S. Patent No. 5,697,970 (hereinafter the '970 patent), entitled "Thinly Woven Flexible Graft";

that we have reviewed and understand the specification of the accompanying reissue
application, including the claims;

that we believe that we are the original and first inventors of the subject matter which is
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that we acknowledge our duty to disclose to the U.S. Patent and Trademark Office all
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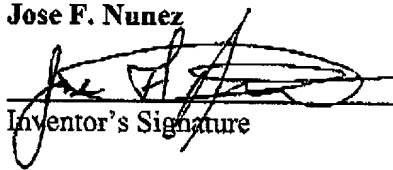
Peter J. Schmitt

Inventor's Signature

Date

2 Bubenko Drive, Garnerville, NY 10923
Residence

Jose F. Nunez



Inventor's Signature

12-13-99
Date

2804 Silver Lane, Apt. 209, St. Anthony, MN 55421
Residence

FIG-1

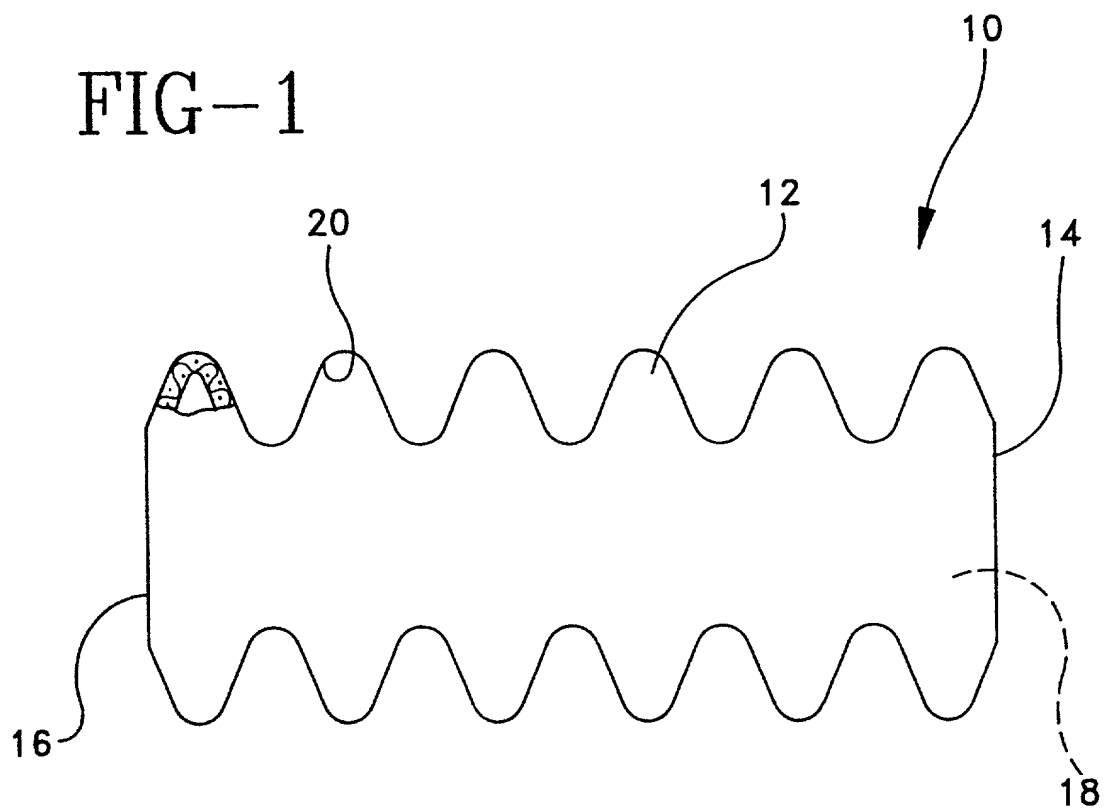


FIG-2

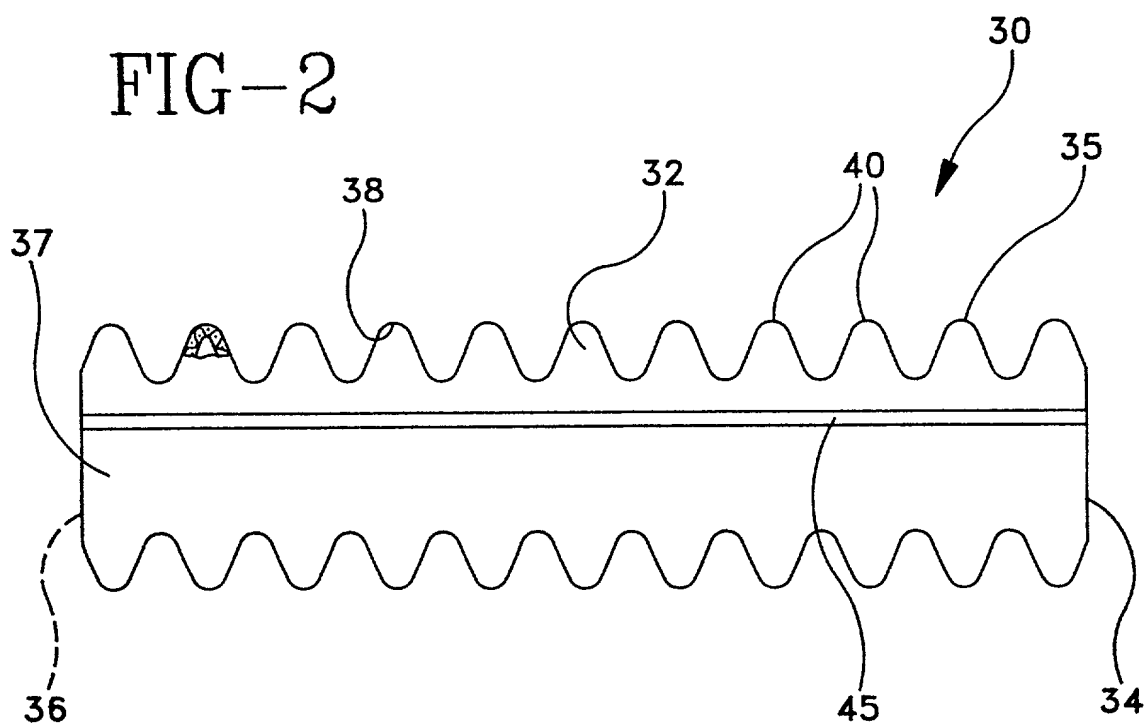


FIG-3

